American Society of Health-System Pharmacist's Presentation at the May 14, 2004, Listening Session of the Drug Importation Task Force

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My name is Douglas Scheckelhoff, and I am the Director, Section of Pharmacy Practice Managers, and Director, Pharmacy Practice Sections of the American Society of Health-System Pharmacists (ASHP). ASHP is the 30,000-member national professional association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care agencies, and other components of health care systems. I am pleased to provide you with ASHP's views on the importation of prescription drugs into the United States.

The American Society of Health-System Pharmacists (ASHP) has a long history of advocating Congress and federal agencies about the importance of maintaining the integrity of our nation's drug distribution system.

For more than 50 years, the US could boast the safest, most tightly regulated system for approving and distributing prescription drugs. Today, there are challenges facing that system. A growing illegal drug trade, including counterfeit medications, rogue Internet sites, and efforts to open US markets to medications imported from abroad have all raised questions regarding the FDA's ability to respond to those challenges..

***Impact of Unapproved Drugs*:** Pharmacists who work in hospitals have to confront this issue. ASHP has received phone calls from pharmacy directors whose hospital administrators have asked them to purchase cheaper drugs from Canada, rather than from U.S. sources. ASHP has referred them to FDA regulations that prohibit that kind of importation. The scope and volume of unapproved drugs entering the United States has raised the concern of ASHP members. That is why ASHP's House of Delegates will vote this June to reaffirm the following policy:

> To oppose importation of pharmaceuticals except in cases in which the Food and Drug Administration determines it would be necessary for the health and welfare of United States

The issue of the safety of our nation's drug supply is being obscured by the issue of allowing individual citizens to purchase prescription drugs at lower prices from overseas locations citizens. While there are no hard data to indicate serious patient harm caused by imported drugs – and it may take years to identify clusters of problems caused by imported medications – the safety perspective must be the highest priority.

There is another factor of the importation issue that has not been addressed adequately, and it relates to foreign terrorism and our nation's counter-terrorism activities. The integrity of the drug supply and the health of consumers is at significant risk if terrorists utilize more lenient importation rules to introduce harmful agents into the United States. Is this not being considered a priority because it has not happened yet? Do we have to wait for something to happen?

•***FDA's Ability to Assure Safety***: The FDA's regulatory system has been the world's "gold standard" of drug approval. To assure the safety of imported products, the FDA will need significantly more resources to examine those products for quality, purity, safety, and effectiveness. Since a significant amount of imported drugs are ordered via the Internet, the agency should consider ensuring the adequate regulation of Internet pharmacy sites.

•***Regulatory/Legislative Issues***: The FDA must have the authority to assure the same level of safety for imported drugs as consumers expect from drugs purchased at a State-licensed pharmacy. There should be no added level of risk that ASHP's members would consider acceptable.

•***Technology***: The FDA's efforts to encourage manufacturers to include track and trace technology into their product packaging for anti-counterfeiting measures should work as well to prevent the importation of unapproved or counterfeited drug products.

•***Financial Impact*:** The FDA must thoroughly study the financial impact of importation to determine whether it would actually lower the cost of drugs for American consumers. Regulations put into place to implement section 1121 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 must not be burdensome to pharmacists and wholesalers. If pharmacists are required to conduct testing and authentication of imported drugs, the majority of our membership would not be able to meet these requirements and still have cost-savings to pass on to the American consumer.

ASHP appreciates the opportunity to comment to the FDA on this significant issue. We are ready to assist the Department of Health and Human Services in any way in developing its policies relating to the importation of prescription drugs.